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Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality /Survey & Certification Group

Ref: S&C: 13-35-NH

DATE: **May 24, 2013**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Advanced Copy: Dementia Care in Nursing Homes: Clarification to Appendix P State Operations Manual (SOM) and Appendix PP in the SOM for F309 – Quality of Care and F329 – Unnecessary Drugs

Memorandum Summary

- **Guidance –** This memo conveys clarification to Appendices P and PP related to nursing home residents with dementia and unnecessary drug use.
- **Training** - Mandatory surveyor trainings are available online at http://surveyortraining.cms.hhs.gov.

National Partnership

On March 29, 2012, the Centers for Medicare & Medicaid Services (CMS) launched the National Partnership to Improve Dementia Care and Reduce Unnecessary Antipsychotic Drug Use in Nursing Homes (this is now referred to as the Partnership to Improve Dementia Care in Nursing Homes). The goal of this Partnership is to optimize the quality of life and function of residents in America's nursing homes by improving approaches to meeting the health, psychosocial and behavioral health needs of all residents, especially those with dementia.

The CMS has joined with various stakeholders to improve dementia care in nursing homes. We are doing several things to support this work, including producing surveyor training videos as well as updating Appendix P and Appendix PP of the State Operations Manual (SOM). Individualized, person-centered approaches may help reduce potentially distressing or harmful behaviors and promote improved functional abilities and quality of life for residents.

It has been a common practice to use various types of psychopharmacological medications in nursing homes to try to address behaviors without first determining whether there is a medical, physical, functional, psychological, emotional, psychiatric, social or environmental cause of the behaviors. Medications may be effective when they are used appropriately to address significant, specific underlying medical or psychiatric causes, or new or worsening behavioral symptoms. However, medications may be ineffective and are likely to cause harm -if given

without a clinical indication. All interventions, including medications, need to be monitored for efficacy, risks, benefits and harm.

The problematic use of medications, such as antipsychotics, is part of a larger, growing concern. This concern is that nursing homes and other settings (i.e. hospitals, ambulatory care) may use medications as a "quick fix" for behavioral symptoms or as a substitute for a holistic approach that involves a thorough assessment of underlying causes of behaviors and individualized, person-centered interventions.

Antipsychotic medications are frequently prescribed for residents with dementia who have behavioral or psychological symptoms of dementia (BPSD).[1,2] The term BPSD is used to describe behavior or other symptoms in individuals with dementia that cannot be attributed to a specific medical or psychiatric cause.

When antipsychotic medications are used without an adequate rationale, or for the purpose of limiting or controlling behavior of an unidentified cause, there is little chance that they will be effective. In addition, they commonly cause complications such as movement disorders, falls, hip fractures, cerebrovascular adverse events (cerebrovascular accidents and transient ischemic events) and increased risk of death. [3,4,5,6] The Food & Drug Administration (FDA) Black Box Warnings Regarding Atypical Antipsychotics in Dementia provides, "Elderly patients with dementia-related psychosis treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo." [7]

Dementia Care Principles

Fundamental principles of care for a resident with dementia include an interdisciplinary approach that focuses on the needs of the resident as well as the needs of the other residents in the nursing home. Sections 1819 and 1919 of the Social Security Act (the Act) and current regulations already require a number of essential elements to be in place in order for facilities to be in compliance with federal requirements on quality of care and quality of life. This revised CMS guidance and surveyor training highlight and re-emphasize a number of those key principles, including:

1. Person–Centered Care. CMS requires nursing homes to provide a supportive environment that promotes comfort and recognizes individual needs and preferences.

2. Quality and Quantity of Staff. The nursing home must provide staff, both in terms of quantity (direct care as well as supervisory staff) and quality to meet the needs of the residents as determined by resident assessments and individual plans of care.

3. Thorough Evaluation of New or Worsening Behaviors. Residents who exhibit new or worsening BPSD should have an evaluation by the interdisciplinary team, including the physician, in order to identify and address treatable medical, physical, emotional, psychiatric, psychological, functional, social, and environmental factors that may be contributing to behaviors.

4. Individualized Approaches to Care. Current guidelines from the United States, United Kingdom, Canada and other countries recommend use of individualized approaches as a first line intervention (except in documented emergency situations or if clinically contraindicated) for BPSD.[8-10] Utilizing a consistent process that focuses on a resident's individual needs and tries to understand behavior as a form of communication may help to reduce behavioral expressions of distress in some residents.

5. Critical Thinking Related to Antipsychotic Drug Use. In certain cases, residents may benefit from the use of medications. The resident should only be given medication if clinically indicated and as necessary to treat a specific condition and target symptoms as diagnosed and documented in the record. Residents who use antipsychotic drugs must receive gradual dose reductions and behavioral interventions, unless clinically contraindicated, in an effort discontinue these drugs.

> **NOTE:** If during a survey, the team identifies a concern that an antipsychotic medication may potentially be administered for discipline, convenience and not being used to treat a medical symptom, the survey team should review F222 - 483.13(a) Right to be Free From Chemical Restraints.

6. Interviews with Prescribers. None of the guidance to surveyors should be construed as evaluating the practice of medicine. Surveyors are instructed to evaluate the process of care. Surveyors interview the attending physician or other primary care provider (NP, PA), behavioral health specialist, pharmacist and other team members to better understand the reasons for using a psychopharmacological agent or any other interventions for a specific resident.

7. Engagement of Resident and/or Representative in Decision-Making. In order to ensure judicious use of psychopharmacological medications, residents (to the extent possible) and/or family or resident representatives must be involved in the discussion of potential approaches to address behavioral symptoms. These discussions with the resident and/or family or representative should be documented in the medical record.

Guidance Updates and Surveyor Training

1. Surveyor training videos

Through work with our partners, CMS has developed a series of interactive training sessions around behavioral health and dementia care. Materials currently available to surveyors may be accessed on the surveyor training website at: http://surveyortraining.cms.hhs.gov/index.aspx.

We have made available three mandatory surveyor trainings (see S&C memo 13-34-ALL). The first training provides an overview of dementia care and potential approaches to addressing behavioral distress. The second training walks surveyors through portions of an annual survey and focuses on the evaluation of one resident with dementia. These two trainings are currently available on the surveyor training website. A third training video is under development that will provide a review of the revised interpretive guidance at F309 and changes to Table 1 for antipsychotic medications at F329. This final training will present case studies and discuss how

to identify potential F Tags and determine severity for non-compliance related to care of a resident with dementia.

2. Updates to Appendix P (Attachment A) include:

- Changes to the resident sampling process for the traditional survey (changes to QIS were included in the recent 10.1.3 release).

The change is intended to ensure that the survey sample includes an adequate number of residents with dementia who are receiving an antipsychotic medication. See Attachment A.

3. Updates to Appendix PP (Attachment B) include:

- A new section of interpretive guidance at F309 related to the review of care and services for a resident with dementia;
- Revisions to the antipsychotic medication section of Table 1 at F329;
- New severity example at the end of the interpretive guidance at F329 (Unnecessary drugs);

A surveyor checklist that may be used in either the traditional or QIS process (modeled after the CE pathways) is also provided (Attachment C). This checklist is not part of the SOM.

References:

1. Briesacher BA, Limcangco MR, Simoni-Wastila L et al. The quality of antipsychotic drug prescribing in nursing homes. Arch Intern Med 2005;165(June):1280-1285.

2. Levinson DR. Medicare Atypical Antipsychotic Drug Claims for Elderly Nursing Home Residents. Department of Health and Human Services Office of Inspector General Report (OEI-07-08-00150)05-04-2011 accessed at https://oig.hhs.gov/oei/reports/oei-07-08-00150.pdf

3. Schneider L, Tariot P, Dagerman K. Effectiveness of atypical antipsychotic drugs in residents with Alzheimer's disease. N Engl J Med 2006;355:1525-1538.

4. Ray WA, Chung CP, Murray KT, et al: Atypical antipsychotic drugs and the risk of sudden cardiac death. N Engl J Med 2009;360:225—235.

5. Schneider LS, Dagerman K, Insel PS: Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. American Journal of Geriatric Psychiatry 2006 14:191—210.

6. Rochon P, Normand S, Gomes T et al. Antipsychotic therapy and short-term serious events in older adults with dementia. Arch Intern Med 2008;168:1090-1096.

7.http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm053171.htm

8. The American Geriatrics Society. (2012). American Geriatrics Society Updated Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. Journal of American Geriatrics Society. New York. The American Geriatrics Society.

9. 3rd Canadian Consensus Conference on Diagnosis & Treatment of Dementia. (2007). Approved Recommendations. Montreal.

10. Scottish Intercollegiate Guidelines Network. (2006). Management of Patients with Dementia: A National Clinical Guideline. Scott Intercollegiate Guidelines Network.

Attachments: 3

Attachment A – SOM – Appendix P – Revision to Sample Selection for the Traditional Survey

Attachment B – SOM – Appendix PP – F309 – Interpretive Guidance for Care and Services of a Resident with Dementia; F329 – Interpretive Guidance for Drug Regimen Free from Unnecessary Drugs (includes only revised sections of F329, including Table 1, section on antipsychotic medications and the new severity example)

Attachment C – Surveyor Checklist for Review of Care and Services for a Resident with Dementia (This document is not considered a SOM revision or addition.)

For questions on this memorandum, please contact Michele Laughman at dnh_behavioralhealth@cms.hhs.gov.

Effective Date: This policy is in effect immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

Training: This policy should be shared with all appropriate survey and certification staff, their managers and the State/Regional Office training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management